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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,304	09/10/2004	Oded Nahleili	1268-234	4417

22429 7590 06/21/2006

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No.	Applicant(s)	
	10/507,304	NAHLEILI, ODED	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 22-26, 28 and 29 is/are allowed.
6) ☒ Claim(s) 1-21, 27 and 30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/7/06; 4/24/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 4/7/06 have been fully considered and are persuasive, however, new grounds of rejection apply. Note that the rejection in view of Nissenkorn has changed to correspond to applicant's claim amendments.

Allowable Subject Matter

Claims 22-26, 28, 29 are allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 21, the configuration is unclear. Please direct to the figures and specification showing "at least one wing-like flap and a plurality of axially folded flaps arranged in a circular array."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 5, 8-15, 20, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al (3,818,511).

Goldberg et al teaches:

1. (currently amended) A stent for use in the oral cavity, said stent being an elongate member and comprising:

an enlarged proximal portion 24, 23 at a proximal end of the stent; and

a bore extending through said stent from said proximal end to a distal end of the stent;

said enlarged proximal portion comprising:
a proximal rim 24 adapted for being located adjacent an oral cavity; and
at least one aperture other than said bore, radially inwardly spaced from said rim,
and adapted for suturing said stent to said oral cavity, in use. Note element 24 is a
woven skirt which inherently has bores, note the abstract teaching the skirt is to enable
suture.

Regarding the function language “for use in the oral cavity” and “rim adapted for
being located adjacent an oral cavity”, Goldberg et al teaches the device
“accommodation to various sizes of vessels, ducts, or conduit” wherein it is within the
scope of the teaching a size that could fit the intended use.

Regarding at least claim 2, see element 7 or the suture taught in the abstract.

Regarding claim 15, “adapted for at least one of local and systemic delivery”
does not positively claim anything.

Claims 1, 2, 6, 8-15, 20, 27, and 30 are rejected under 35 U.S.C. 102(b) as being
anticipated by Nissenkorn (4,973,301).

Nissenkorn teaches:

1. (currently amended) A stent for use in the oral cavity, said stent being an
elongate member and comprising:
an enlarged proximal accordion-like portion 6 at a proximal end of the stent; and
a bore extending through said stent from said proximal end to a distal end of the
stent;

said enlarged proximal portion comprising:
a proximal rim (inherent end of the tube) adapted for being located adjacent an oral cavity; and
at least one aperture 13 other than said bore, radially inwardly spaced from said rim, and adapted for suturing 19 said stent to said oral cavity, in use.

Regarding claim 7, see flaps 5.

Regarding the length, see 3:4, teaching 40-80 mm.

Regarding at least claims 10-13, Nissenkorn teaches a diameter of about 16-20 French (French = $\pi \times \text{diameter}$).

Regarding claim 20, see element 34.

Claims 1-5, 7, 10-15, 27, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Donowitz et al (3,788,327).

Donowitz et al teaches:

1. (currently amended) A stent for use in the oral cavity, said stent being an elongate member and comprising:

an enlarged proximal portion 34 at a proximal end of the stent; and
a bore extending through said stent from said proximal end to a distal end of the stent;

said enlarged proximal portion comprising:

a proximal rim adapted for being located adjacent an oral cavity; and

at least one aperture 44 other than said bore, radially inwardly spaced from said rim, and adapted for suturing said stent to said oral cavity, in use.

The device is fully capable of fulfilling the function language "for use in the oral cavity" and "rim adapted for being located adjacent an oral cavity".

Regarding claim 3, see wing-like flap 46.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al, Nissenkorn, or Donowitz et al.

The three references are described above, however, they are silent regarding the claimed materials according to claims 16-19. It would have been obvious to one having ordinary skill in the art have applied the claimed materials, for example, as a coating to each of the medical devices of Goldberg et al, Nissenkorn, or Donowitz et al for the well know medical response of said material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

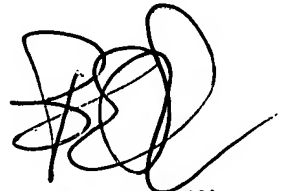
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

Art Unit: 3738

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes



BRUCE SNOW
PRIMARY EXAMINER